INTERAGENCY MEETING ON FEDERAL RESEARCH
INTO THE BIOLOGICAL EFFECTS OF IONIZING RADIATION
National Institutes of Health
Building 1, Room 114
Bethesda, Maryland 20205
Friday, March 2, 1979
1:30 to 3:00 P.M.

AGENDA

I. Introduction--Dr. Donald S. Fredrickson

II. Review of the Draft Charter--Meeting Participants

III. Review of Proposal for Study by the NAS

- Survey of Current Government Studies--Dr. Robert S. Gordon, Special Assistant to the Director, NIH
- Discussion by Participants

IV. Conclusion--Dr. Fredrickson

MEETING OF INTERAGENCY REPRESENTATIVES CONCERNED WITH THE BIOLOGICAL EFFECTS OF IONIZING RADIATION

Minutes of the First Meeting
March 2, 1979

The first interagency meeting on Federal research into the biological effects of ionizing radiation was held Friday, March 2, 1979, at the National Institutes of Health. Dr. Donald S. Fredrickson, NIH Director, chaired the meeting, and Dr. Joseph G. Perpich, Associate Director for Program Planning and Evaluation, served as executive secretary.

The purpose was to review certain mandates based on Congressional and Presidential directives and given to Dr. Fredrickson by Secretary Califano. Representatives had been recommended by Mr. Peter Libassi, General Counsel for HEW, who chairs the Interagency Task Force on the Health Effects of Ionizing Radiation. Prior to the meeting, all representatives were sent two documents: a draft charter for a proposed new committee, The Interagency Committee on Federal Research Into the Biological Effects of Ionizing Radiation, and a draft letter from Dr. Fredrickson to the National Academy of Sciences (NAS) requesting a study of Federal programs.

Scope of the Committee's Mandate

Dr. Fredrickson opened the meeting with a brief review of Congressional and HEW initiatives and then discussed the tentative charter for the Committee. One of the first issues considered was the scope of research

to be covered. It was noted that the proposed charter reads "biological effects" rather than "human effects," raising a question of emphasis. Would the Committee cover both human and animal studies, including animal husbandry and the like? Dr. Fredrickson said the emphasis would be on human epidemiologic studies, but a wider range of biological effects was to be encompassed. A number of Committee members agreed that animal studies must be included, particularly in view of their relevance to human effects, but the Committee would not have an interest in animals per se. It was agreed that the scope of research as cited in the charter would not be changed.

Another issue related to what standard would be used for determining low-level ionizing radiation for purposes of the Committee's mandate. Dr. McIndoe, DOD, asked whether the definition of "low-level" was less than 5 rems per year. Dr. Mills, EPA, suggested that the limit not be rigidly set, as much good information for purposes of the Committee's task would be excluded. After some discussion, it was agreed that while reference points would be needed later, there should be initial agreement on goals rather than tasks and no limit set yet on the level of ionizing radiation to be investigated. Dr. Upton, NCI, pointed out that the primary focus of the Committee will be to look at radiation from particular sources, occupational and environmental, and that the objective will be a better understanding of low-dose exposure.

Discussion of Committee Charter

Representatives then turned to the statement of function in the charter. The statement focuses on the need for a research strategy and priorities, as well as for selecting the loci where the research should be conducted. Several questions were raised about the term "select appropriate loci and recommend allocation of resources. . . ." One person asked whether it was envisioned that the Committee would have authority to conduct research programs or whether it was solely advisory. Dr. Fredrickson emphasized that it would be advisory.

In response to the question whether the Committee would review the infrastructure of agencies to determine which laboratories should be doing which work, Dr. Fredrickson said the Committee would look generally rather than deeply into agency structures, and would assist in the coordination of research in various program areas. Coordination (meaning information exchange and a search for agreement on goals, strategies, and specific approaches) was to be stressed, but there was need for some agencies to take the lead in the allocation of efforts. After further discussion, it was generally agreed that the phrase "select appropriate loci" would be changed to "identify appropriate loci" as more consistent with an advisory committee.

Another question concerned the clause "By the authority of the Secretary, all Agencies are required to consult with the Committee. . . ." Dr. Fredrickson explained that the charter had been written for an HEW rather than an interagency committee. It was agreed that the ultimate authority for a Federal committee would be the President. It was also

suggested that the clause "all Agencies are required to consult with the Committee" be changed to "all Agencies agree to consult with the Committee." Dr. Fredrickson concurred, believing the Committee must try to act by consensus as much as possible.

Questions were raised concerning the Committee's role in reviewing projects while a research strategy is being developed over the next year and a half. Dr. Dickson, OASH, noted that if the Committee is to review and approve proposals, there must be some strategy in mind, yet it is planned to take over a year to build one. Dr. Fredrickson agreed that the problem exists, but believes that the Committee must be monitoring studies while the strategy is under review.

Further discussion centered on the possible options for achieving coordination of Federal programs--from merely providing agency consultation to requiring formal Committee review and approval of all agency-proposed studies. Dr. Liverman, DOE, asked whether the Committee is going to ensure that all useful information from past studies will be used. Dr. Silverman, FDA, expressed concern about adding yet another layer of approval required in the Government before epidemiologic studies can be done, and pointed to the long delays in launching research now. Dr. Fredrickson noted in response that we were not to try to create a direct supervisory role. He suggested the intermediary option that agencies agree to consult with the Committee and take its comments into account. There was approval of that as part of the Committee's mandate.

Dr. McIndoe, DOE, asked where the comments of the Committee would go--whether they would have an effect. Will the Committee address the question of budgets, for example? In response, Dr. Fredrickson noted that the comments would go to the individual agency involved. It should be assumed that the Committee's comments might also go to the President--presumably to the OMB--and the Congress. Thus agency budgets could be affected indirectly but the Committee certainly wouldn't be expected to develop a Federal budget for research in the subject area, or otherwise to override individual mission responsibilities.

In summary, Dr. Fredrickson noted that there appeared to be general agreement with the mandate of the Committee as modified--that the Committee should study proposals and comment on them to the agencies and to the relevant Executive Branch officials to whom the Committee is advisory. He noted also that in assuring a basis for confidence in research and regulation in the radiation area, the Committee was dealing with a problem that affected the public perceptions of all Federally supported science.

Dr. Fredrickson asked if there were further comments on the Committee or its mandate. Dr. Budnitz, NRC, commented that the charter needed a preamble stating why we want to know about the biological effects of ionizing radiation. It should take into account the many agencies represented. In response, Dr. Fredrickson asked that the agency participants send in brief statements to be incorporated into the preamble. Another question was whether OSHA had been invited to the meeting; and Dr. Fredrickson said it had not, that only agencies with research components

had been invited to this meeting, but that OSHA's needs and concerns should also be stated in the preamble.

NAS Studies

Dr. Fredrickson briefly reviewed the Congressional mandate for studies of Federal research programs in radiation. Copies of the Congressional material were distributed. The mandate to HEW is that all Federal research programs in the subject area be reviewed and that a research strategy be developed.

Dr. Mills, EPA, asked how these efforts could be synchronized with the NAS's ongoing study of the Department of Energy. Dr. Fredrickson noted that he had met with President Handler and other NAS staff, who agree that if we move expeditiously the NAS could incorporate the study of all Federal research programs as part of its overall study of DOE research. He noted that the thrust of the overall NAS study should be toward the scientific content of programs rather than toward their management.

In response to questions about the proposed research strategy to be developed by the Federal Committee, Dr. Fredrickson said that the BEIR III report, 1/ which the Academy will release shortly, and the UNSCEAR report 2/ can serve as the basis for developing the proposed strategy,

1/ The third report of the Advisory Committee on the Biological Effects of Ionizing Radiations, by the Division of Medical Sciences, National Academy of Sciences-National Research Council.

2/ Sources and Effects of Ionizing Radiation, United Nations Scientific Committee on the Effects of Atomic Radiation, 1977 report to the General Assembly with annexes: United Nations, N.Y. (725 pp.).

which could then be subjected to critique by the NAS. Dr. Fredrickson emphasized that the Committee rather than the Academy would be responsible for developing the strategy, since the latter has only an advisory role. It was asked whether research gaps should be addressed to enhance the critique of the proposed Federal strategy, and Dr. Fredrickson agreed that this would be an important task for both the Federal Committee and the NAS.

Conclusion

Dr. Fredrickson introduced Robert Gordon, a Special Assistant, who chairs an NIH Epidemiology Committee. Dr. Gordon is working with NCI representatives to review all Federal epidemiologic studies and to determine whether better information can be obtained for purposes of the Federal Committee. He displayed two charts that categorize all the current studies collated by the Science Work Group of the Interagency Task Force. He requested the agencies' cooperation in responding to a questionnaire he would develop and send to them for their review, to get more information on the studies. There was general agreement to participate in the survey, which would be limited to studies on human health effects.

Dr. Fredrickson concluded the meeting by thanking all agency representatives for their participation and cooperation. He noted that another meeting would undoubtedly be called within a month, and asked any agencies contemplating new studies to inform him and the other members of the

interagency group, especially if the study is a large epidemiologic one.

The meeting was adjourned at 3:05 p.m.

Respectfully submitted,

Joseph G. Perpich, M.D., J.D.
Associate Director for
Program Planning and Evaluation

National Institutes of Health
Bethesda, Maryland 20205

April 6, 1979

Interagency Meeting on Federal Research
Into the Biological Effects of Ionizing Radiation
List of Attendees
March 2, 1979

DEPARTMENT OF DEFENSE

Colonel USAF, MC Darrell W. McIndoe
Director
Armed Forces Radiobiology Research
Institute

DEPARTMENT OF ENERGY

Dr. James L. Liverman
Deputy Assistant Secretary for
Environment

ENVIRONMENTAL PROTECTION AGENCY

Dr. William H. Ellett
Chief
Bioeffects Analysis Branch

NUCLEAR REGULATORY COMMISSION

Mr. Karl R. Goller
Director, Division of Siting,
Health and Safeguards Standards

Mr. Robert Purple
Assistant Director for Radiological
Health and Safeguards Standards

Mr. Saul Levine
Director
Office of Nuclear Regulatory Research

Dr. Robert J. Budnitz
Deputy Director
Office of Nuclear Regulatory Research

Dr. Shlomo Yaniv
Technical Assistant to the Director
Division of Safeguards and
Environmental Research

VETERANS ADMINISTRATION

Dr. Lawrence Hobson
Deputy Assistant Chief Medical
Director for Research and
Development

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE GENERAL COUNSEL

Ms. Linda F. Donaldson
Office of the General Counsel

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Dr. James F. Dickson III
Senior Advisor
for Environmental Affairs, OASH

Dr. Harold Margulies
Special Assistant for
Environmental Health, OASH

OFFICE OF HEALTH RESEARCH, STATISTICS, AND TECHNOLOGY

National Center for Health Statistics

Dr. Paul E. Leaverton
Associate Director for Research
Office of Statistical Research

CENTER FOR DISEASE CONTROL

Dr. Glyn G. Caldwell
Bureau of Epidemiology

National Institute for Occupational Safety and Health

Dr. John R. Froines
Deputy Director

FOOD AND DRUG ADMINISTRATION

Bureau of Radiologic Health

Mr. John C. Villforth
Director, BRH

Dr. Charlotte Silverman
Deputy Director, BRH

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Dr. Donald S. Fredrickson
Director

Dr. Robert Gordon
Special Assistant to the Director

Dr. Joseph G. Perpich
Associate Director for
Program Planning and Evaluation

National Cancer Institute

Dr. Arthur C. Upton
Director

National Institute of Environmental Health Sciences

Dr. David P. Rall
Director